

Subpart B—Reimportation

§ 203.10 Restrictions on reimportation.

No prescription drug or drug composed wholly or partly of insulin that was manufactured in a State and exported from the United States may be reimported by anyone other than its manufacturer, except that FDA may grant permission to a person other than the manufacturer to reimport a prescription drug or insulin-containing drug if it determines that such reimportation is required for emergency medical care.

§ 203.11 Applications for reimportation to provide emergency medical care.

(a) Applications for reimportation for emergency medical care shall be submitted to the director of the FDA District Office in the district where reimportation is sought (addresses found in § 5.115 of this chapter).

(b) Applications for reimportation to provide emergency medical care shall be reviewed and approved or disapproved by each district office.

§ 203.12 An appeal from an adverse decision by the district office.

An appeal from an adverse decision by the district office involving insulin-containing drugs or prescription human drugs, other than biological products, may be made to the Office of Compliance (HFD-300), Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855. An appeal from an adverse decision by the district office involving prescription human biological products may be made to the Office of Compliance and Biologics Quality (HFM-600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852.

Subpart C—Sales Restrictions

§ 203.20 Sales restrictions.

Except as provided in § 203.22 or § 203.23, no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity; or

(b) Donated or supplied at a reduced price to a charitable organization.

§ 203.22 Exclusions.

Section 203.20 does not apply to:

(a) The purchase or other acquisition of a drug for its own use by a hospital or other health care entity that is a member of a group purchasing organization from the group purchasing organization or from other hospitals or health care entities that are members of the organization.

(b) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control.

(d) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons.

(e) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a valid prescription.

(f) The sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug by hospitals or health care entities owned or operated by Federal, State, or local governmental units to other hospitals or health care entities owned or operated by Federal, State, or local governmental units.

(g) The sale, purchase, or trade of, or the offer to sell, purchase, or trade blood or blood components intended for transfusion.

§ 203.23 Returns.

The return of a prescription drug purchased by a hospital or health care entity or acquired at a reduced price by or donated to a charitable institution is exempt from the prohibitions in § 203.20, provided that:

(a) The hospital, health care entity, or charitable institution documents the return by filling out a credit memo specifying:

(1) The name and address of the hospital, health care entity, or charitable institution;